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09/246,468 02/09/99 REBEK

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EXAMINER

GARCIA, M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1627

DATE MAILED:

06/20/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

File copy

Office Action Summary

Application No.
09/246,468

Applicant(s)

Rebek et al

Examiner

Maurie E. Garcia, Ph. D.

Group Art Unit

1627



☒ Responsive to communication(s) filed on May 15, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire THREE month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-15 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-15 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

1. The Response filed May 15, 2000 (Paper No. 6) is acknowledged. Claims 16-34 were cancelled and no claims were amended or added. Therefore, claims 1-15 are pending.

2. Applicant's election without traverse of Group I (claims 1-15) in Paper No. 6 is acknowledged. Applicant's further election of species is also acknowledged. However, upon further consideration, the examiner withdraws the species election requirement. Therefore, claims 1-15 are examined on the merits.

3. The examiner would like to point out that the elected species is free of the prior art. Also, an expanded search indicates that claims 3 and 5-15 are also free of the prior art. The following objections/rejections are made, however.

Drawings

4. This application has been filed with informal drawings, which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed. The drawings are objected to by the draftsman under 37 C.F.R. 1.84 or 1.52. See PTO-948 for the details of these objections. Correction of the noted defects in the drawings can only be deferred until the application is allowed by the examiner.

Claim Objections

5. Claim 15 is objected to because of the following informalities:

The claim is objected to because the chemical entities in the structural formulas recited in the claim are crowded too closely together, making reading of the entities difficult. A substitute claim is required.

Claim Rejections - 35 USC § 101/112 - Lack of Specific Utility

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-15 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well-established utility.

9. According to the text of 35 USC sec. 101, an invention must be “useful”. Our reviewing courts have applied the labels, “specific utility” (or “practical utility”) to refer to this aspect of the “useful invention” requirement of sec. 101. (Nelson v. Bowler, 626 F.2d 853, 206 USPQ 881, 883 (CCPA 1980)). In Nelson, the Court characterized “specific utility” (or “practical utility”) as “a shorthand way of attributing real-world

value to claimed subject matter. In other words[, the claimed subject matter will be deemed to have utility if one skilled in the art can use the] claimed discovery in a manner which provides some immediate benefit to the public.” (Id. at 856.)

10. The only utility disclosed for the instant compounds is that they can be used as core molecules for use in constructing a combinatorial library. These libraries are further screened to determine whether - or not - any of the compounds contained within the libraries possess some exploitable biological activity. See, for example, the instant specification, page 4, line 14 through page 5, line 2; page 6, lines 4-11; and page 13, line 12 through page 14, line 3. Therefore, the issue for the claimed compounds under this statute is whether the fact that the claimed compounds can be used to create combinatorial libraries that can be can be screened, without more, constitutes an “immediate benefit to the public”. The analysis proceeds on two levels. On a first level, an issue is whether any of the claimed compounds are of an immediate benefit to the public. On a second level, an issue is whether the claimed use of the compounds as core molecules for constructing a combinatorial library represents a specific asserted utility. As will be seen from the following discussion, the claimed compounds provide no immediate benefit to the public and the claimed use does not qualify as a specific asserted utility.

11. With respect to the individual compounds, it is clear that the specification discloses no specific exploitable biological (or other) activity for any of the compounds

that would render them of an immediate benefit to the public. The specification suggests that libraries of such compounds be screened for such activity, but does not report that any of the compounds possess an exploitable activity.¹ On the contrary, whether any of the compounds possess such an activity is entirely speculative. Indeed, it is possible, according to the specification as a whole, that none of the compounds will turn out to have any useful activity. Applicants have left to others this burden of determining by means of screening whether any of the compounds will amount to more than mere objects of scientific inquiry². Therefore, as to the individual compounds, there is no disclosed specific utility.

12. On the second level of analysis, the claimed use of the compounds as core molecules for constructing a combinatorial library also would not provide an immediate benefit to the public as such is not a specific asserted utility. The specification states that the benefit that the libraries provide the public is their usefulness as “research tools.” See the specification, at page 13, lines 12-13, and elsewhere: “A combinatorial library of this invention is useful for rapidly generating and developing large numbers of drug candidate molecules.” While research tools have long been recognized as being patentable subject matter, there is also a well-recognized distinction between research tools and the objects

¹ Had the specification taught that any of the compounds had a useful activity, then those compounds would be of immediate benefit to the public. The other compounds would then enjoy a rebuttable presumption that they also possess the specified activity. The burden would be on the USPTO to assert, by a preponderance of the evidence, that the proposed utility is not credible. MPEP 2107.

² Note, because the claimed invention is not supported by a specific asserted utility for the reasons just set forth, credibility cannot be assessed.

of research. Thus, while telescopes, microscopes, gas chromatographs, screening assays, and the like, are examples of research tools that enjoy unquestioned utility (MPEP 2107(I) second column), chemical entities, with no disclosed (and no generally well known) useful activity do not.

13. Thus, one must distinguish between inventions that have a specifically identified utility and inventions whose specific utility requires further research to identify or reasonably confirm. The claimed compounds (and combinatorial libraries made therefrom) fall into this latter category. Giving them labels such as “research tool,” “intermediate” or “for research purposes” does not without more impart specific utility to the invention if, by such labels, it is meant that the invention is merely the object of further research. MPEP 2107(I), second column. As the claimed compounds (and the libraries made therefrom) are in practice objects of further research, they cannot fairly be characterized as “research tools” in the same sense as a microscope or gas chromatograph. Therefore, on the second level of analysis, the claimed compounds do not have a specific asserted utility.

14. In the absence of an asserted specific utility, the “useful” requirement may be established by reference to a well-established utility. MPEP 2107.01(II)(B). A “well established utility” is a “specific utility” which is well known, immediately apparent and implied by the specification based on the disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. The claimed compounds are not

supported by a well-established utility, however, because neither the specification as filed nor any art of record discloses or suggests any property or activity for the compounds such that another non-asserted utility would be well established for the compounds. Further, the compounds are not recognizable as analogous to compounds with a recognized pharmacological (or other) activity. In the absence of any data as to their activity, there is no basis upon which to base either a specific or a well-established utility.³ However, the following should be noted as it pertains to the art cited below.

15. The base structure of the claimed core compound (where R and R₁ = H) is well known in the art but has no well-established utility of its own, being as this compound has been used in a variety of other syntheses (for example, see US 3,071,591, cited below). It should be noted that the prior art teaches using this compound to create compounds that have completely different substituent patterns than those set forth in claims 3 and 5-15 and therefore would not suggest that the claimed compounds had similar activity to those compounds known in the prior art. Additionally, the core compound and several variants are known in the art as starting materials for the creation of synthetic host molecules (for example, see Smeets et al, cited below). These synthetic

³ Note that a "well established utility" cannot alternatively be based upon a "throw away" utility that one can dream up for an invention, or upon a utility that would obviously apply to virtually every member of a very general class of materials. If this were the case, any product or apparatus, including perpetual motion machines, would have a "well established utility" as landfill, an amusement device, a toy, or a paper weight, any carbon containing molecule would have a "well established utility" as a fuel since it can be burned, and any protein would have well established utilities such as manufacturing supplements for vitamins or food, as protein supplements for animal food, or as an animal poison in the protein is toxic. This is clearly not the intention of the statute.

host molecules represent research tools for studying host-guest chemistry, which also does not constitute a patentable well-established utility.

16. Claims 1-15 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 1, 2 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Paterson, L.O. (US 3,071,591).

Paterson teaches “new compounds of glycoluril and their methods of manufacture”, namely N-halogenated glycolurils (see column 1, lines 6-9). These halogenated glycoluril compounds are used as disinfecting and bleaching agents (column 1, lines 25-31). These compounds are made using glycoluril starting materials that read on the compound of the instant claims when R and R₁ = H. See the structure in column 1 lines 58-68 and specifically the

compound used in Example 3. The starting material of Example 3 (column 3, lines 11-23) is 3a,6a-diphenyl-glycoluril, which is the exact compound claimed.

19. Claims 1, 2 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Smeets et al (J. Org. Chem. 1989, Vol. 54, pp. 3710-3717).

Smeets et al teaches "the synthesis of organic hosts" which are basket-shaped molecules (see Abstract). These basket-shaped molecules (see Figure 1) are used to investigate host-guest interactions (see, for example, Table II). These compounds are made using glycoluril starting materials that read on the compound of the instant claims when R and R₁ = H. See the structure in Scheme 1 page 3710, which is the exact compound claimed.

Status of Claims/Conclusion

20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Rudkevich et al. Angew. Chem. Intl. Ed. Engl. 1997, 36(8), pp. 846-848. The reference discloses compounds similar in structure to those claimed. No patentable utility is disclosed in this reference.

21. No claims are allowed.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie E. Garcia, Ph.D. whose telephone number is (703) 308-0065. The examiner can normally be reached on Monday-Thursday from 9:30 to 7:00 and alternate Fridays.

23. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie E. Garcia, Ph.D.
June 16, 2000

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